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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,945	08/27/2003	Itzhak Bentwich	05-0007#2/cat	1944

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,945	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/10/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Comply with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See, for example, the sequences listed in Figures 12A, 13A, 14A, and paragraph 0151 of the instant specification. The requirements of 37 CFR §§1.821 through 1.825 requires the submission of a computer readable form sequence listing, a paper copy for the specification, a statement under 37 CFR §§1.821(f) and (g), and SEQ ID Nos cited along with each sequence listed in the specification or Figures.

The submission of a computer readable form (CRF), submitted by applicants on 01/10/2005, for sequences disclosed in paragraph 0151 of the instant specification is acknowledged, however the CRF does not contain a listing for the sequences disclosed in Figures 12A, 13A, and 14A. Further, the specification does not contain SEQ ID Nos cited along with each sequence disclosed in either the specification or Figures.

Applicants are also reminded that SEQ ID Nos are not required in the Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or notice of a failure to fully respond to this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11, 12, and 14, drawn to a bioinformatically detectable novel gene, a vector comprising said novel gene, a probe comprising said novel gene, and a vector inserter comprising said probe and a gene expression detector, classified in class 536, subclass 24.5. A further sequence election and species election identified below are also required if this group is elected.

II. Claims 9 and 10, drawn to a method of selectively inhibiting translation of at least one gene, classified in class 514, subclass 44. A further sequence election identified below is also required if this group is elected.

III. Claim 13, drawn to a method of selectively detecting gene expression of at least one gene, classified in class 436, subclass 6. A further sequence election identified below is also required if this group is elected.

IV. Claims 15-20, drawn to an anti-viral substance and method of anti-viral treatment capable of neutralizing RNA encoded by a bioinformatically detectable novel gene, classified in class 435, subclass 5. A further sequence election identified below is also required if this group is elected.

The inventions are distinct, each from the other because of the following reasons:

Group I and Groups II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Group I is drawn to a nucleic acid product that is a bioinformatically detectable novel gene including vectors and probes thereof. Group II and III are drawn to methods of using the nucleic acid product of Group I. Group II is drawn to and reads on a method of treatment and requires inhibition of at least one gene in a cell. Group III is drawn to an assay method of detecting gene expression. In the instant case, the product as claimed can be used in a materially different process of using that product. In regards to groups I and II, the product may be used in a method of hybridization, to detect gene expression. In regards to groups I and III, the product may be used in a method of inhibiting gene expression by inhibiting translation.

Furthermore, search and examination of Group I with either of Groups II or III would impose a serious and undue burden. In the instant case, prior art searches of methods of treatment (or of methods of inhibiting gene expression in vitro) and of methods of detecting gene expression would not be coextensive with a prior art search of the claimed compound(s). Search of each of these inventions would require different key word searches of each method that would necessarily include a search for the distinctive method steps of each that would be different for each and that would not be required in a search of the compound(s). These searches would have to be performed using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature,

placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of Group I with either of Groups II or III.

Inventions of Group IV and Groups I-III are directed to related products and processes involving a novel bioniformatically detectable gene. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Invention of Group IV is directed to anti-viral substances and methods of anti-viral treatment capable of neutralizing RNA encoded by the novel bioinformatically detectable gene as recited in the invention of Group I, and therefore distinct from the gene itself. Further, methods of anti-viral treatment are not commensurate in scope with the methods selectively inhibiting translation or of selectively detecting gene expression as recited in Groups II and III, respectively, as each of said methods involve distinct functions and have different effects. The search required for the invention of Group IV would not be coextensive with the search required for the inventions of Group I-III, as anti-viral substances and methods of anti-viral treatment are not required in novel bioinformatically detectable genes or in methods for selective identification or inhibition of translation thereof. Therefore, the search required for Group IV together with any of Groups I-III would present an undue burden of search.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include

the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Sequence Election Requirement for All Groups

In addition to the above restriction requirement, all the groups in the instant application read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences. For each sequences, the Applicants must elect a single sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one sequence is elected. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 36 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Species Election regarding Target Genes in Group I

Claims 1-8, 11, 12, and 14 (Group I) are generic to the following disclosed patentably distinct species of target genes. The species (target gene sequences) are independent or distinct because the sequences are unrelated. Applicant is required

under 35 U.S.C. 121 to elect a single disclosed species (a single target gene that must be the target of the elected gene), even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

EDJ EDJ

17 March 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER